

as pellets was higher than those with other formulations. Patients starting with a patch demonstrated the highest switching rate compared to other formulations.

PDB150

PATTERNS OF MEDICATION USE IN THE ONE YEAR FOLLOWING INITIATION OF DPP-4 INHIBITORS IN THE UNITED STATES

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OBJECTIVES: DPP-4 inhibitors produce a modest improvement in HbA1C with relatively few adverse effects. Little is known about the characteristics and treatment patterns of patients receiving DPP-4 inhibitors in the US. The objectives of the current study were to characterize patients prescribed DPP-4 inhibitors and examine patterns of anti-diabetic medication use in the one year following their initiation. **METHODS:** Data were obtained from Humedica's National Electronic Health Record-Derived Longitudinal Patient-Level Database (2007–2011). The study cohort included all adult patients with T2DM who received a first prescription for a DPP-4 inhibitor during the study period and who had at least one HbA1C value at baseline. Baseline patient demographics, clinical characteristics and anti-diabetic medication use in the one-year follow-up period were assessed. Cox proportional hazard models were used to assess independent predictors of the aggregate outcome of switching or augmentation. **RESULTS:** Of the 8700 patients in the study cohort, 84% were older than 50, and 52% were female; the mean BMI was 34.4 and mean HbA1c at baseline was 7.81%. Overall, 2226 (25.6%) patients switched or augmented therapy within the first year following DPP-4 inhibitor initiation after a mean of 6.1 months; the most frequently observed patterns included a switch to another oral agent (n=1791, 20.6%) or to insulin (n=306, 3.5%). Higher baseline HbA1C (HR 1.20 [95% CI 1.14–1.26] for HbA1C >9% vs. <7%) and higher BMI (HR 1.11 [95% CI 1.06–1.16] for BMI ≥30 vs. 25–29) predicted higher rates of switching/augmentation, while female gender (HR 0.92 [95% CI 0.89–0.95]) and younger age 0.42 [95% CI 0.22–0.81]) predicted lower rates. **CONCLUSIONS:** In this US cohort, change in anti-diabetic treatment was relatively uncommon in the one year following initiation of a DPP-4 inhibitor. Baseline characteristics including HbA1C, BMI and demographics can be used to inform the likelihood of switching or augmentation.

PDB151

EVALUATION OF ASSOCIATION BETWEEN DIABETES RELATED QUALITY MEASURE ACHIEVEMENT AND DIABETES COMPLICATIONS IN A MEDICARE ADVANTAGE POPULATION

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OBJECTIVES: Centers for Medicare and Medicaid Services (CMS) assess the performance of health insurance plans using quality of care measures. This study assessed achievement of 8 diabetes-related quality measures at the patient level and examined whether achievement was associated with fewer complications. **METHODS:** Claims and member-level quality data between January 2010 and December 2011 were obtained from a Medicare Advantage Prescription Drug Insurance provider. Patients with type 1 or type 2 diabetes on the index date (January 1, 2011) and with 12 months of pre- and post-index continuous enrollment were included. Quality of care and diabetes complications were assessed during the post-index year. The impact of quality metric achievement on new or worsening diabetes complications was assessed with a logistic regression model, which adjusted for baseline characteristics. **RESULTS:** Cohort size ranged from 159,454 to 4,464, depending on the quality measure and patient-level data availability. Most patients (>80%) achieved LDL-C screening, nephropathy assessment, and medication adherence standards. Over 99% of patients met dosing standards for biguanides, sulfonylureas, and thiazolidinediones. Eye screening and use of appropriate anti-hypertensive treatments had lower achievement levels (50.3% and 54.2%, respectively). A majority (61%) of patients achieved HbA1c<9%; 29% of patients achieved LDL-C control <100mg/dl. Logistic regression estimates showed that failure to reduce HbA1c below 9% statistically significantly increased the risk of new or worsening diabetes complications [(OR, 1.12 (95% CI, 1.10–1.15); p<0.0001] as did failure to use anti-hypertensive treatment [(OR, 1.40, (95% CI, 1.24–1.59); p<0.0001]. **CONCLUSIONS:** Data from a 1-year observation period suggests that attainment of CMS diabetes quality metrics was associated with lower new or worsening complication risk. Since the full impact of improved care may not be properly assessed within such a short time, follow-up longitudinal studies would shed light on the long-term impact of achieving quality measures.

PDB152

A REGULATORY COMPARISON OF NON-INSULIN DEPENDENT TYPE II DIABETES DRUG APPROVALS IN THE UNITED STATES AND EUROPEAN UNION

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OBJECTIVES: In 2012, Downing et al published a novel study in the NEJM that compared the speed of regulatory agencies between 2001–2010, which demonstrated the FDA's relative quickness. This paper narrows the scope to new non-insulin dependent type II diabetes drugs approved by the EMA and FDA (using their respective websites) during 2005–2013, accounting for new drug approvals and legal updates to regulatory systems in a disease condition that has faced a plethora of regulatory challenges. **METHODS:** Unlike Downing, this study looks at the European Commission's (EC) decision, instead of the Committee for Medical Products for Human Use's (CHMP) recommendation. A Marketing Authorization is issued upon EC decision, making it analogous with the data captured surrounding the FDA's approval process. Additionally this analysis looks at the date submitted to the FDA and EMA as well as the approval date. The data consists of 12 non-insulin dependent moieties approved between 2005 and 2013. **RESULTS:** Out of the 12 new treatments, 10 were approved first by the FDA (83%). Additionally, the FDA began reviews before the EMA with a median time of 126.5 days. The FDA also completed 8 of the 12

regulatory reviews faster than the EMA while beginning regulatory review first in each case. Three of the four regulatory decisions in which the FDA was slower were outliers in terms of approval time. Additionally, when looking at the median, the FDA approved these moieties 77 days faster than the EMA while Downing's findings only showed a 44-day differential. This was expected because the analysis included the EC decision takes about 2 months on average. **CONCLUSIONS:** After updating the data, restricting it to a particular subset of diabetes treatments, and altering the EMA regulatory endpoint, Downing et al's findings not only still hold true, but become even more pronounced.

PDB153

DELAYED TREATMENT MODIFICATIONS FOR PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM) WITH VERY POOR GLYCEMIC CONTROL

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OBJECTIVES: Risk of cardiovascular disease, retinopathy, nephropathy, and neuropathy increases substantially when HbA1c>7% (suboptimal glycemic control), but timely therapy intensification may reduce risk. When HbA1c>9% (very poor control) AACE recommends that triple therapy (asymptomatic patients) or insulin (symptomatic patients) be initiated to reach HbA1c≤6.5% for patients without concurrent illness and at low hypoglycemic risk. Clinical inertia (failure to intensify therapy in a timely manner) leads to poor glycemic control. The objective of this study was to examine time to treatment modifications in patients with HbA1c≥9%. **METHODS:** Medical, laboratory, and pharmacy claims data for Humana's fully insured commercial and Medicare membership were used for this study. Patients with T2DM with first HbA1c≥9% date (index-date) between Jan 1, 2008–Dec. 31, 2009 were identified. Baseline characteristics were obtained within 12 months preceding the index-date. Treatment modification was defined as addition or switch of an antidiabetic drug class. Study outcome (delay in treatment modification) was assessed as the days until modification within the 36-months post-index period. **RESULTS:** There were 8,464 patients identified (mean age 66 years, 48% male, 82% from the southern US, mean Deyo-Charlson Comorbidity Index 2.54, mean Diabetes Complications Severity Index 2.17). Approximately 83% of patients experienced modification within 36 months; 47% within 90 days of HbA1c≥9% index date, 7% between 91–180 days, 5% between 181–365 days, while 24% were >365 days. Around 20% of patients received insulin as a modification. Although the proportion of patients receiving triple therapy (≥3 classes) was still low (23%) at 12 months post-index, it increased from 10% at baseline. **CONCLUSIONS:** Many patients in poor control receive insufficient therapy as recommended by treatment guidelines. Even though additional agents were added for some patients, those receiving insulin or triple therapy were low. For patients with HbA1c≥9%, prompt treatment intensification is needed to improve glycemic control and limit complications.

PDB154

COST IMPLICATIONS OF EARLY DISCONTINUATION AND RESTART OF INSULIN IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS

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OBJECTIVES: This study examined different types of medical costs associated with early discontinuation (ED) of insulin therapy and with restarting of insulin among ED patients in the treatment of type 2 diabetes mellitus (T2DM). **METHODS:** Truven's Health Analytics Commercial Claims and Encounters database from 1/1/08 through 12/31/11 were utilized. ED was defined as discontinuation of insulin therapy for at least 30 days in the first 90 days post initiation. Generalized linear models with log-link were used to examine the association between ED and total medical costs, acute care (hospitalization and emergency room) costs, outpatient costs, diabetes-related drug costs and all-cause drug costs. Among ED patients, the association between restarting insulin therapy and costs were also examined. Analyses controlled for patient characteristics, index medication prescribed, patient general health, comorbidities, prior resource utilization, and prior medication utilization. **RESULTS:** Most (82% of 74,399) individuals discontinued insulin therapy in the first year post initiation and 75% of these patients were ED. Compared to non-ED, ED was associated with 9.6% higher acute care costs (P=0.0003), while outpatient costs, diabetes-related drug costs, all-cause drug costs and total medical costs were all significantly lower among ED patients. Among the ED cohort, 90% restarted therapy over the post-period, with 53% restarting within 4 months. Compared to non-restart, the restart of insulin therapy after ED was associated with 11.3% higher acute care costs (P=0.033), 24.0% higher outpatient costs (P<0.001), 80.2% higher all-cause drug costs (P<0.001, and 30.3% higher total medical costs (P<0.001). **CONCLUSIONS:** Current findings suggest that during the first three months following initiation of insulin therapy for T2DM, the ED of insulin therapy and its restart are associated with higher acute care costs. Such costs are often considered avoidable or modifiable costs and tend to signal poorer long-term treatment outcomes.

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NATIONAL PATTERNS IN PRESCRIPTION MEDICATION TREATMENT FOR DIABETES: 2002-2010

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OBJECTIVES: To compare recent trends in treatment pattern for diabetes between 2002 and 2010. **METHODS:** A cross-sectional study of expenditures was carried for representative sample of civilian, noninstitutionalized U.S. individuals with diabetes from the Medical Expenditure (MEPS) 2002–2010. Expenditures include all sources of payment for oral anti-diabetic medications, insulin, and non-insulin injectables. We inflated 2002 dollar values to 2010 values using the consumer price index. **RESULTS:** From 2002 to 2010, the estimated number of persons reporting